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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,283	10/09/2001	Joy M. Campbell	P05272US0	5786

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EXAMINER

EWOLDT, GERALD R

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/973,283

Applicant(s)

CAMPBELL ET AL.

Examiner

G. R. Ewoldt, Ph.D.

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003 and 14 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-112 is/are pending in the application.
- 4a) Of the above claim(s) 46,50,54-58 and 60-112 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45,47-49,51-53 and 59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's election without traverse of Group I by the cancellation of all product claims in the paper filed 12/22/03 is acknowledged. Applicant's election with traverse of the species: (A) a method of regulating the immune response in an animal comprising orally administering an immunoglobulin composition to an animal (claim 45), (B) pig, and (C) blood, in the paper filed 6/14/04 is acknowledged.

Applicant argues that a search of all of the claims could be made without serious burden, in particular, Applicant argues that the search regarding the individual animals or sources of immunoglobulin would place no undue burden on the Office.

These arguments are not found persuasive for the following reasons. While the search of the individual species may overlap, they are not coextensive. Whereas one reference might teach the method of the claims being performed employing one animal, it might be silent regarding another. Likewise, the search for the use of immunoglobulins from one source would not necessarily yield results regarding immunoglobulins derived from a different source. Accordingly, a showing of noncoextensive searches has been accepted by the Office as a showing a serious search burden on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 46, 50, 54-58, and 60-112 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species.

Claims 45, 47-49, 51-53, and 59 read on the elected invention and are being acted upon.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 45, 47-49, 51-53, and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically:

A) In Claim 45, the phrase "regulating the immune response" is vague and indefinite as it is undefined. To regulate can be defined as to direct, control, or adjust, however these definitions do not correlate with the method of the instant specification which discloses only the lowering of serum Ig levels. Accordingly, the claim is considered to be vague and indefinite as it is unclear what further "regulation" of the immune system is intended to be encompassed by the claim.

B) In Claim 52, the term "cross-species source" is vague and indefinite as it is undefined in the specification and not well-known in the immunological arts.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 45, 47-49, 51, 53, and 59 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Borg et al. (1999, IDS).

Borg et al. teaches a method of "regulating" the immune response in a pig comprising administering to said pig a immunoglobulin composition in said pig's water supply (see entire Abstract). Note that the claims also recite the lowering of serum IgG, this effect, however, is inherent to the method of the reference.

The reference clearly anticipates the claimed invention.

7. Claim 52 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Borg et al. (1999, IDS) as evidenced by American Protein Corp. (APC) SOLETEIN™ Material Safety Data Sheet (MSDS).

Borg et al. teaches a method of "regulating" the immune response in an animal comprising administering to said animal a immunoglobulin composition wherein the source of the immunoglobulin composition is a "cross-species source" (see entire Abstract and page 2 of the MSDS). Note that both the abstract and the MSDS are found on APC's internet website. Clearly they both refer to the use of APC's immunoglobulin composition product SOLETEIN™. As the MSDS indicates that the product may comprise an "allergen to those allergic to bovine

products", and the major components of the product are animal serum, globulin and plasma, it is clear that the product comprises a "cross-species" source of IgG in the instant context.

The reference clearly anticipates the claimed invention.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 45, 47-49, 51, 53, and 59 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, "a method of regulating the immune response".

Upon careful review of the specification no support has been found for the broadening of the claimed invention, i.e., the specification discloses only a method of lowering serum Ig levels.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.


Please Note: Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR

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or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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8/12/04
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